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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,742	01/08/1999	FREDRIC R. BLOOM	042270031US0	7763

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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/227,742

Applicant(s)

BLOOM ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 45-59 and 61-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 45-59, 61-72, 76, 77 and 81-84 is/are rejected.
- 7) ☐ Claim(s) 73-75 and 78-80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 July 2002 has been entered.

This action is also in response to the supplemental response filed 30 September 2002 which set forth new arguments in response to the pending rejections.

Claims 45-59 and 61-84 are pending.

Oath/Declaration

1. Applicant's desire to continue to hold the matter of the Oath/Declaration in abeyance is noted; however, the present Oath/Declaration remains defective for the reasons made of record in the Office action mailed 12 April 1999, Paper #2.

In addition to the reasons made of record in Paper #2, the priority claim to provisional application 60/025,838 is incorrectly listed as "06/025,838". Since a new oath or declaration is to be provided, it is suggested that the priority claim to non-provisional application 08/826,426 also be provided.

Response to Amendment

2. Claims 45-59 and 61-71, and newly added claims 81-84, stand rejected under the judicially created doctrine of obviousness-type double patenting for the reasons made of record in the Office actions mailed 22 September 1999, 5 June 2000 and 5 June 2001. Applicant's willingness to file a Terminal Disclaimer (p. 4, amendment filed 5 December 2000) is noted; however the rejection is maintained in the absence of said disclaimer.

3. The rejection of claims 72 and 80 under 35 U.S.C. §112, first paragraph, as lacking written description has been withdrawn, as noted in the Advisory action mailed 10 August 2002.

The rejection of claims 72-80 under 35 U.S.C. §112, second paragraph, as being indefinite, has been withdrawn, as noted in the Advisory action mailed 10 August 2002.

The rejection of claims 72, 76 and 77 under 35 U.S.C. §102(b) as being anticipated by Bogoslovakaia et al (Zh. Mikrobiol. Epidemiol. Immunobiol. (1984) 12:65-68) has been withdrawn in view of Applicant's new arguments provided in the supplemental response filed 30 September 2002.

4. New grounds of rejection are set forth below.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

7. Claims 72, 76 and 77 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bogoslovakaia et al (Zh. Mikrobiol. Epidemiol. Immunobiol. (1984) 12:65-68) in view of Sambrook et al ("Preparation and Transformation of Competent *E. coli*" in Molecular Cloning A Laboratory Manual, Sambrook et al, eds, Cold Spring Harbor Laboratory Press, 1989, pp. 1.74-1.84), Binger et al (USP 5,661,015) and Ron (USP 4,404,186).

Bogoslovakaia et al teach *E. coli* possessing a membrane having an increased unsaturated fatty acid content relative to total fatty acid content, relative to the same *E. coli* prior to increasing its unsaturated fatty acid content. In the Table on p. 66 there are listed several strains of *E. coli* and their fatty acid composition as a function of time of growth in hours (which spans the log rhythmic and steady state periods of growth). Also listed is the percent survivability of each strain in the air at each time of growth. In

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particular, there is strain GA9 and three GA9 strains comprising different plasmids. The following table summarizes the relevant data from the table; the final column was calculated by summing the % unsaturated fatty acid (16:1 ω 7; 16:1 ω 9; and 18:1 ω 7) and dividing by the total fatty acid (100%) and multiplying by 100 to get the percentage of unsaturated fatty acid relative to the total fatty acid content.

Strain	Growth time in hours	% survivability in air	% unsaturated fatty acid
GA9	7.5	0.25%	34%
	26.5	1.93%	12%
GA9/pSA25	7.5	0.11%	44%
	26.5	10.81%	26%
GA9/pSA50	7.5	6.5%	42%
	26.5	9.12%	27%

As the table clearly illustrates, GA9/pSA25 and GA9/pSA50 each have increased % unsaturated fatty acid compared to parental strain GA9. While it is not disclosed what is encoded on the plasmids pSA25 and pSA50, it is nonetheless clear that as a result of the plasmid, each strain has an increased unsaturated fatty acid content. Since each of these E. coli strains possesses the single structural feature recited in the claim (a membrane having an increased unsaturated fatty acid content relative to total fatty acid content), it is believed that the property of enhanced transformation ability will be

inherent to the bacteria. Bogoslovakaia et al do not teach making either GA9/pSA25 or GA9/pSA50 competent.

Sambrook et al teaches making competent *E. coli* cells wherein one step involves storage of the cells on ice for 10 minutes. See p. 1.77, Step 7. Ice is about 0°C.

Binger et al teach the use of *E. coli* transformed with a construct expressing an antigen of an *Eimeria* surface antigen as a live vaccine for vaccination of poultry. *Eimeria* is an intracellular protozoan parasite which causes coccidiosis in poultry which is a very costly diseases for poultry farmers. See entire document, especially col. 2, lines 8-9, col. 3, lines 8-10 and col. 18, lines 26-33.

Ron teaches the use of *E. coli* as live vaccines for vaccination of poultry and mammals. Ron teaches that a pronounced advantage of live vaccines is that they can be administered as aerosols. See entire document, especially col. 2, lines 25-26.

At the time the invention was filed, it would have been obvious to one of ordinary skill in the art to make competent either strain of Bogoslovakaia et al having an increased % of unsaturated fatty acid in the membrane. One of ordinary skill in the art would have been motivated to do so in order to prepare a live vaccine comprising a vector expressing an antigen for a costly disease in poultry and using a bacteria which has an increased survivability in air would be advantageous because it would improve the efficacy of aerosol administration by increasing the number of surviving microbes per aerosol dose.

Conclusion

Claims 45-59, 61-72, 76, 77 and 81-84 are rejected. Claims 73-75 and 78-80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

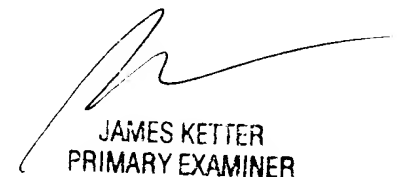
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

December 15, 2002



JAMES KETTER
PRIMARY EXAMINER